

REMARKS

Status

Claims 1-7 and 9-20 will be pending upon entry of the present amendment. No new matter will be added upon entry of the amendments.

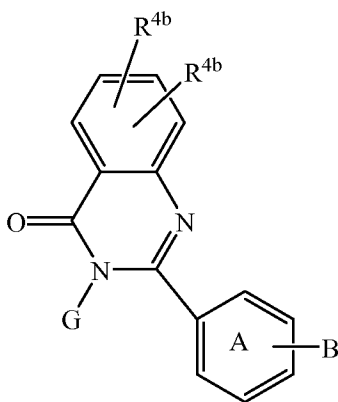
Discussion

The rejection of Claims 1, 2, 14, and 15 under 35 U.S.C. §102(b) over Pandit et al (CA 79:115526) has been obviated by appropriate amendment.

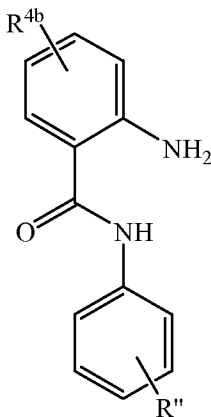
As noted in the Office Action, the species of Pandit et al requires the presence of a pyrimidyl ring. Pyrimidyl has been removed from the definition of ring A. Consequently, the presently claimed invention should not be considered anticipated by Pandit et al. Withdrawal of this rejection is respectfully requested.

The rejection of Claims 1-7 and 14-21 under 35 U.S.C. §112, 1st paragraph has been obviated by appropriate amendment.

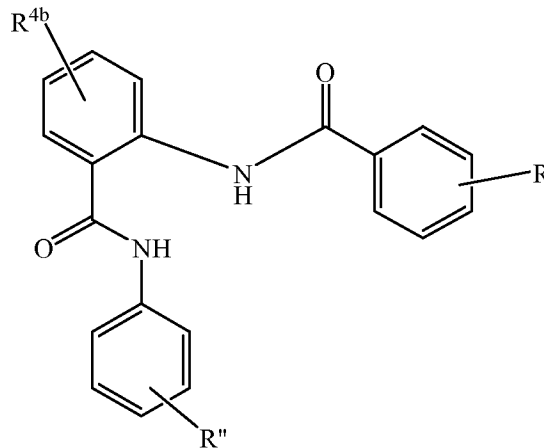
Applicants have limited the presently claimed invention to the quinazolin-4-ones shown below, wherein both ring G and ring A are independently a phenyl or pyridyl ring.



Presently Amended Formula I



3



4

The Office Action on page 3 states that the specification enables compounds wherein G is phenyl or pyridyl and A is biphenyl or methoxy-phenyl. The Action continues by saying that the specification “does not reasonably provide enablement for the mak[ing] and us[ing] of compounds of formula I wherein G is another ring [i.e., not phenyl or pyridyl] while A-B is a *phenyl group substituted with a heterocycle.*” (Emphasis in original.) The presently

amended claims only cover compounds where G is phenyl or pyridyl. Thus, the reference to a lack of enablement for compounds where G is “another ring” no longer applies.

If the Office Action were referring to a lack of enablement for compounds where G is phenyl or pyridyl and A is a substituted phenyl or pyridyl (e.g., a heterocycle substituent), then Applicants strenuously and respectfully disagree. As formulas 3 and 4 above show, in order to make compounds of the present invention, one need only combine an appropriately substituted benzoic acid or pyridyl-carboxylic acid with the phenyl- or pyridyl-aminocarbonyl-phenylamine of formula 3. The Office Action has already acknowledged that the compounds of formula 3 are enabled. Applicants submit that it is well within the skill of an organic chemist to prepare the desired substituted benzoic acid or pyridyl-carboxylic acid compounds. For example, a quick search of Aldrich.com reveals that there are 119 entries for “pyridine carboxylic acids” and 1825 entries for “benzoic acids.” Thus, there are literally thousands of commercially available compounds precursors. If the USPTO doesn’t agree that the starting materials for the presently claimed invention are well known, then it is respectfully requested that specific substituents be selected and shown to be outside the purview of an organic chemist.

With respect to use of the presently claimed compounds, Applicants respectfully note that factor Xa inhibitors are very well known (e.g., see US Patent Nos. 5998424, 6339099, 6413980, and 6429205). Assays to test for factor Xa are well known and at least one of which is described in the above-identified application. Furthermore, factor Xa inhibitors are currently in clinical trials here in the U.S. A simple search at Google.com shows that Apixaban, Enoxaparin, and DX-9065a, all factor Xa inhibitors, are all currently in clinical trials. Use of factor Xa inhibitors would have to be conceded to be well known. As the USPTO knows, it is not an applicants’ burden to point to a specific compound that can be developed into a marketed drug-such an effort falls under the purview of the FDA, not the USPTO. Applicants need only show how to make and use the compounds of the present invention. In light of the currently amended claims, the high level of skill in the art of organic synthesis, the plethora of factor Xa patents (and publications), and the high level of skill in the selection and clinical development of factor Xa inhibitors, Applicants submit that the presently amended claims are enabled. Withdrawal of the §112, 1st paragraph, rejection is respectfully requested.

The rejection of Claims 1-6, 14-19, and 21, now 1-6 and 14-19 under 35 U.S.C. §112, 2nd paragraph, has been obviated by appropriate amendment. The following paragraph designations refer to those provided on pages 6-7 of the Office Action.

a. Applicants have removed the phrase “*alternatively, when 2 R groups are attached to adjacent atoms, they combine to form methylenedioxy or ethylenedioxy*”.

Withdrawal of this rejection is respectfully requested.

b. The reference to Z in the definition of B has been removed. Withdrawal of this rejection is respectfully requested.

c. Claim 21 has been cancelled. Withdrawal of this rejection is respectfully requested.

Restriction Response

Applicants have now limited the claims to the combination of Groups 1 and 2, wherein ring G is phenyl or pyridyl. With the present amendment, the presently claimed compounds of formula 1 have been narrowed only correspond to 4 cores (G is phenyl or pyridyl, A is phenyl or pyridyl, and the central core is a quinazolinone). When considering structural isomerism, there are actually only 3 cores: (1) G and A are both phenyl, (2) one of G and A is pyridyl, or (3) both G and A are pyridyl. In view of the discussion of enablement, it appears that the USPTO has already considered compounds where G is pyridyl (group 2) and phenyl (group 1). Thus, Applicants respectfully request that these two groups be combined into one and that the entire subject matter of the presently claimed invention be considered.

With respect to withdrawn claims 9-13, Applicants respectfully request rejoinder of these claims once allowable subject matter has been found in claim 1, in accordance with the provisions of MPEP § 821.04.

In view of the foregoing, Applicants submit that the application is now in condition for allowance. Early notification of such action is earnestly solicited. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

Respectfully submitted,

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/jing g. sun/
Jing G. Sun, Ph.D.
Registration No. 45,914
Telephone No. (609) 252-3791
Facsimile No. (609) 252-4526

Please forward all future written correspondence relating to this application to:

Louis J. Wille
Patent Department
Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000